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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/436,513	11/09/99	JONES	J 3290.007US1
			EXAMINER

HM12/0125

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ART UNIT	PAPER NUMBER
PATTERSON, C	9

1652

DATE MAILED: 01/25/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5/27/00 & 11/20/00

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-62 is/are pending in the application.
☐ Of the above, claim(s) 21-50 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-20 & 51-62 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☒ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 1 P24-2
☐ Interview Summary, PTO-413
☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Applicant's election with traverse of Group I, claims 1-20 and 51-62 in Paper No. 8 is acknowledged. The traversal is on the grounds that there would not be a serious burden upon the examiner in examining all of the groups since all of the groups use the hydrolase of Group I and a search for prior art for Group I would also find prior art relevant to the methods of Groups II-IV. This is not found persuasive because there is more to examining claims than simply prior art. The issue of 35 USC § 101 and 112 also have to be considered. Also, there is no assurance that a search for Group I would necessarily uncover all of the prior art for Groups II-IV. It is maintained that there would be a serious burden upon the examiner to examine all of the groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-50 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 8.

Applicants have labeled the IDS filed 5/23/00 as "Supplemental Disclosure Statement". However, there is not another IDS of record.

The disclosure is objected to because of the following informalities:

On page 9 the Brief Description Of The Drawings does not contain a description of Figure 1. Also, the description of Figure 6C refers to "217C" when apparently the correct recitation should be "L217C".

On page 10, line 29 the recitation of "are not limited to Rick to provide all serine hydrolase including enzymes" is not understood.

Appropriate correction is required.

Claims 12, 13, 58 and 59 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 58 are incorrect in the recitation of "a disaccharides" on line 2. The correct recitation is "a disaccharide".

Claim 13 and 59 are indefinite and confusing in that patent claims should be as complete as possible in themselves and not incorporate references to a figure (see MPEP 2175.05(s)).

Claims 1-20 and 51-62 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No In Figure 3 the recitation of "(R)-5 = MOM" is not understood. What is meant by the abbreviation "MOM"? In Figure 4 the recitation of "(R)-16 R = Bn" is not understood. What is meant by the abbreviation "Bn"?

Figure 6A, which is apparently supposed to convey the data in Table 1 for N62C derivatives, is apparently incorrect. For instance, the amidase value of N62Ca should apparently be $218/226 = 0.96$ and the amidase value of N62Ce should apparently be $458/308 = 1.48$. Applicant

has plotted on Figure 6A values of approximately -0.04 and + 0.4.

This is not understood. An explanation is required.

Why have the wild type subtilisin, the modification by replacing the wild type residue with a non-modified cysteine (e.g. N26C) and some of the modified cysteine replacements (e.g. N62C-c) not be assayed against (R) and (S) substrates as apparently the other enzymes have?

Table 2 is not understood. Why is there a value listed under the fifth and ninth columns ("assay") for the three modified enzymes but not the WT? What are the values in the second rows of some columns of the enzymes such as "4", " ± 0.05 ", " ± 180 ", " ± 0.07 ", " ± 540 ", "2", " ± 0.01 ", etc.?

The chemical structures in claims 14, 20 and 60 are not disclosed in the specification. While the examiner can follow some of the names such as "2-methoxy-2-phenyl-ethyl-thiol" he cannot follow all of them. Applicants should add the chemical names to the appropriate portions of the specification if they cannot show that it already contains these names.

Claims 1-20 and 51-62 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for transesterification activity of *Bacillus lentus* subtilisin having modifications L217C-S-(CH₂)₂-SO₃⁻, N62C-S-(CH₂)₂-SO₃⁻ and N62CH₃⁻ (as shown in Table 4), does not reasonably provide enablement for claims of the scope now claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant specification teaches in Example 2, pages 46-49, that these three modified enzymes that were formed by replacing a Cys for another residue and then modifying the substituent group of the Cys, catalyze transesterifications. It does not show that they catalyze transamidations or transpeptidations or that any other substituent changes such as Table 1 or 2 catalyze transesterifications. Furthermore, the specification does not teach one anything about other modified subtilisins or more broadly other modified serine hydrolases.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 15-18 and 51-58 are rejected under 35 U.S.C.

§ 102(a,b) as being anticipated by either of Berglund, et al. (A or C2), Davis, et al. (C3), DeSantis, et al. (C4).

Berglund, et al. (A) teach replacing a Met in a *Bacillus lentus* subtilisin with a Cys and modifying the Cys as shown in structure "3" on page 2508. This is an "alkyl amino group with a positive charge". Berglund, et al. (C2) teach adding the same substituent (R=k).

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Davis, et al. teach adding Cys modified by glycosylation.

DeSantis, et al. teach at least the same modification as Berglund, et al.

It is noted that claims 12, 18 and 58 further define claims 11,17 and 57 but do not further limit it.

Claims 1-4, 11-12 and 51 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bech, et al. (C1).

Bech, et al. teach at least the Cys derivatives Bz1S-Cys, AeS-Cys and Pha-Cys, which meet the requirements of the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., Ph.D. whose telephone number is (703) 308-1834. The examiner can normally be reached on any day of the week from 7:30 AM until 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Patterson
January 24, 2001


CHARLES L. PATTERSON, JR.
PRIMARY EXAMINER
GROUP 1800

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